Testing Mechanical Countermeasures for Cephalad Fluid Shifts

Completed Technology Project (2015 - 2017)

Project Introduction

Current evidence suggests that NASA's spaceflight-associated neuro-opthalmological syndrome (SANS/VIIP) risk is related to an elevation in intracranial pressure (ICP) during spaceflight, either consequent to or aggravated by cephalad fluid shifts in microgravity. From recent data, SANS occurs in >50% of astronauts, to varying degrees, and can lead to long term visual changes. Although its cause is unknown, its importance is high enough to motivate studies of potential countermeasures. The key objectives of this project were therefore: (1) to test and help validate two commercial devices as mechanical countermeasures for cephalad fluid shifts to potentially treat elevated ICP, (2) identify any potential adverse consequences during use or following release of such countermeasures, and (3) optimize deployment procedures for such countermeasures.

The Russians currently use Braslet—an elastic thigh band—to help sequester blood in the legs and alleviate symptoms resulting from cephalad fluid shifts. While promising, this device has not been tested as a SANS countermeasure. Lower body negative pressure (LBNP) is an alternative approach, which draws fluid into the legs using vacuum mechanism. Both have drawbacks, however. Braslet devices are custom-built, difficult to obtain, and have limited calibration options. LBNP is typically bulky and hence could only be used at limited times. As an alternative to Braslet, we tested the Kaatsu thigh cuff system. This commercially available system is designed for enhanced muscle training on Earth. In addition, we investigated use of a LymphaPress compression garment configured to provide a vascular resistance for fluid return from the lower body (as opposed to enhanced fluid return for which the device was designed for clinically). In Experiments 1 and 2 we conducted tests using both countermeasures (at different inflation pressures) in healthy subjects undergoing -6 degrees head-down tilt (HDT). We characterized cerebral blood volume and flow, intraocular pressure, structural eye parameters, and cerebral vascular parameter changes associated with application, maintenance, and following release of each countermeasure. In Experiment 3, we tested the Kaatsu system in neurointensive care unit patients with invasive ICP devices implanted to monitor and treat elevated ICP.

Together, the data from these studies suggested that—at the chosen inflation pressures--neither countermeasure exhibited significant potential as a treatment for, or mitigator of, cephalad fluid shifts and elevated ICP.

Anticipated Benefits

Impact: This project provided the first tests of commercial, user-friendly and safety-tested devices as countermeasures potentially suitable for SANS.

Results include: (1) an assessment of both thigh cuffs and a compression garment as a SANS countermeasure, (2) assessment of the influence of these

Testing Mechanical Countermeasures for Cephalad Fluid Shifts

Table of Contents

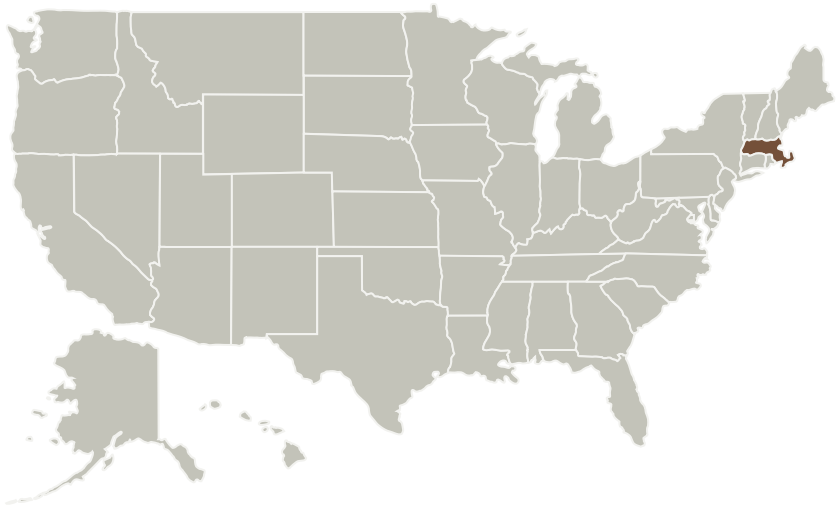
Testing Mechanical Countermeasures for Cephalad Fluid Shifts

Completed Technology Project (2015 - 2017)

devices on cerebrovascular and ocular parameters, (3) parameterization of countermeasure deployment and rebound effects on multiple physiological variables, and (4) information regarding optimized deployment of the countermeasures.

Earth Benefits: Currently, there are few treatment methods for elevated ICP, which affects patients with traumatic brain injury, stroke, hydrocephalus, and cancer patients. None of the current methods involve non-invasive mechanical devices—instead focusing on surgical procedures or medications. This work therefore has the potential to identify one or more countermeasures and/or protocols—within a novel class of countermeasures—that could be used to help manage intracranial fluids and pressure. Since these approaches do not require drugs, they avoid the potential side effects, drug-drug interactions, or longer-lasting effects that often come from medication use.

Primary U.S. Work Locations and Key Partners



Organizational Responsibility

Responsible Mission Directorate:

Space Operations Mission Directorate (SOMD)

Lead Organization:

National Space Biomedical Research Institute (NSBRI)

Responsible Program:

Human Spaceflight Capabilities

Project Management

Program Director:

David K Baumann

Principal Investigator:

Gary E Strangman

Co-Investigators:

Eric Bershad
Chethan Venkatasubba Rao
Eric Rosenthal
Aaron Dentinger
Adam M Cohen
Aaron Baggish
Quan Zhang

Testing Mechanical Countermeasures for Cephalad Fluid Shifts

Completed Technology Project (2015 - 2017)

Organizations Performing Work	Role	Type	Location
National Space Biomedical Research Institute(NSBRI)	Lead Organization	Industry	Houston, Texas
Baylor College of Medicine	Supporting Organization	Academia	Houston, Texas
GE Global Research	Supporting Organization	Industry	Niskayuna, New York
Massachusetts General Hospital	Supporting Organization	Industry	Charlestown, Massachusetts

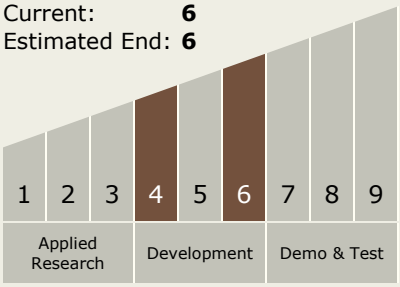
Primary U.S. Work Locations
Massachusetts

Project Transitions

June 2015: Project Start

Technology Maturity (TRL)

Start: **4**
Current: **6**
Estimated End: **6**



Technology Areas

Primary:

- TX06 Human Health, Life Support, and Habitation Systems
  - TX06.3 Human Health and Performance
    - TX06.3.2 Prevention and Countermeasures

Target Destinations

The Moon, Mars

Testing Mechanical Countermeasures for Cephalad Fluid Shifts

Completed Technology Project (2015 - 2017)

May 2017: Closed out

Closeout Summary: Current evidence suggests that NASA's spaceflight associated neuro-opthalmological syndrome (SANS/VIIP) risk may be related to an elevation in intracranial pressure (ICP) during spaceflight compared to the upright position on Earth, either consequent to or aggravated by cephalad fluid shifts in microgravity. The key objectives of this project were: (1) to test and assess two commercial devices as mechanical countermeasures for cephalad fluid shifts and modify cerebral and/or ocular parameters, (2) to identify any potential adverse consequences during use or following release of such countermeasures, and (3) to optimize deployment procedures for such countermeasures. Specifically, this project sought to test the Kaatsu thigh cuff muscle training system, as an alternative to the Braslet, and a reconfigured Lymphapress system, originally designed for fluid management in edema patients. In year 2 of the project we initiated and completed three human experiments. In Experiment 1, we tested n=18 healthy subjects during a -6 degree head-down tilt protocol. Subjects were monitored during two 3-hour sessions (one for each countermeasure, randomized order) consisting of 20-min periods in each of the following orientations, in sequence: +50 degree HUT (head up tilt), supine, -6 degree HDT, -6 degree HDT during countermeasure deployment, -6 degree HDT post-deployment of the countermeasure, supine, and briefly again at 50 degree HUT. All subjects were tested with Kaatsu at 180 SKU deployment pressure and Lymphapress at 34-36 mmHg pressures, in counterbalanced orders. Experiment 2 tested n=12 healthy subjects identically as in Experiment 1, however, with higher countermeasure pressures: Kaatsu at a deployment pressure of 300 SKU and Lymphapress at pressures of 43-45 mmHg. In Experiment 3, the Kaatsu system was tested in n=5 patients in the NeuroICU in collaboration with Dr. Eric Bershad with invasive ICP monitoring for 20 min baseline, 20 min Kaatsu deployment, and 20 min post-deployment at 250 SKU. Neither of the investigated mechanical countermeasure devices caused adverse effects in subjects and were well tolerated throughout trials. Kattsu cuffs were deemed less obtrusive and more practical to deploy due to their small size and compliance. The Lymphapress system was overall less practical to deploy due to its size and mode of application that required subjects to wear large inflatable compression pants—sufficiently so to preclude their use in NeuroICU patients with unstable ICP in Experiment 3. Experiments 1 and 2 demonstrated significant sequestration of blood in the legs during Kaatsu deployment, whereas Lymphapress deployment did not. No significant changes in cerebral or ocular parameters (cerebral blood volume, cerebral blood flow velocity, intraocular pressure) were observed during or following either countermeasure. We believe the negative findings were in part due to distinct design issues associated with each commercial device.

Stories

Articles in Peer-reviewed Journals
(https://techport.nasa.gov/file/54155)

Project Website:

https://taskbook.nasaprs.com